IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Melanie Stacel

Plaintiff,

v.

Teva Pharmaceuticals USA, Inc.

Defendant.

Case No. 08 C 1143
Honorable Joan Gottschall

PLAINTIFF'S RESPONSE TO DEFENDANT'S MOTION TO DISMISS

Plaintiff respectfully requests that this court deny defendant Teva's Motion to Dismiss. Teva's Motion to Dismiss cites F.R.C.P. 9 and F.R.C.P. 12(b)(6), alleging that plaintiff has failed to plead fraud claims with particularity and that plaintiff's state law claims are pre-empted by federal law because Teva complied with federal law.

Plaintiff pleads her fraud claims with sufficient specificity. Whether Teva complied with federal law is a question of fact.

FACTS

Plaintiff Melanie Stacel was prescribed a generic form of the drug minocycline in July 2004, and from that time forward she regularly took that drug until March 2005. As a result of her ingestion of generic minocycline, Stacel developed drug-induced lupus, and was diagnosed with the disease in September 2005. Stacel's drug-induced lupus was physically and emotionally debilitating, and had severe psychological and financial repercussions. (Exh. A, Plaintiff's Second Amended Complaint at 7 through 15).

Plaintiff alleges three counts. Count I is common law negligence. Count II is common law fraud and misrepresentation. Count III seeks relief under the Illinois Consumer Fraud and Deceptive Business Practices Act.

DISCUSSION

1. Plaintiff's fraud claims in Counts II and III are sufficiently specific and should not be dismissed without allowing plaintiff the opportunity to further investigate those claims through discovery.

The heightened pleading requirements for fraud are well-established. "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." *Harris v. Fleming,* 839 F.2d 1232, 1237 (7th Cir.1988). Plaintiff must "state the time, place and content" of the alleged communications perpetrating the fraud. *Graue Mill Development Corp. v. Colonial Bank & Trust Co. of Chicago,* 927 F.2d 988, 992 (C.A.7 (Ill.),1991)(internal quotation marks omitted).

Plaintiff's complaint meets the heightened standard of Rule 9(b) for pleading fraud. The complaint identifies the time period in which plaintiff was deceived, the substance of the misleading statements and omissions that caused plaintiff's injury, the location in which both plaintiff and defendant were at the time of the fraud, and Teva's fraudulent intent.

The time period is when and before plaintiff consumed the drug. See paragraphs 7, 12, 14, 21, 25, 26 and 29 of the Second Amended Complaint. The place of the false statements is the public domain. See paragraphs 25 and 35 of the Second Amended Complaint. The content of the fraudulent statements is spelled out in paragraphs 22 and 26 of the Second Amended Complaint.

As to Count II of plaintiff's Second Amended Complaint there is sufficient specificity of

plaintiff's pleadings:

25. Defendant Teva made false statements of material fact by not revealing to Plaintiff and others including the public and her physician and/or the FDA of reported cases in which the drug was reported to have caused what is commonly known as lupus.

26. Defendant was careless in making such false statements of material fact to the public via promotional activities, letters of approval to the FDA, labels attached to the prescription for users, dissemination of information to physicians including Plaintiff's physician and failures to ask the FDA to put complete information on the labels that users would be fully informed as to what Defendant knew about the drug could causing lupus in certain persons and by not revealing Defendant's full knowledge about cases of drug induced lupus.

27. The failure of Defendant to reveal full knowledge about this drug causing a lupus condition to Plaintiff, the public and the FDA was intended to cause persons including Plaintiff to purchase the drug.

28. Plaintiff, in reliance of the truth of the statements concerning the drug's safety, took the medication and continued to take the medication without knowledge that it was causing drug induced lupus.

29. Plaintiff, in reliance of the material omission and/or concealment by Defendant of its full knowledge about the drug being reported to cause drug induced lupus, took the drug.

30. Defendant owed a duty to Plaintiff, the public, physicians and the FDA to fully disclose and competently disclose that this drug could cause lupus.

31. As a direct and proximate cause of Defendant's misrepresentations, Plaintiff was injured in that she got lupus from the Defendant's drug.

As to Count III ov plaintiff's second amended complaint there is sufficient specificity:

34. In violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, Defendant committed deceptive acts and practices including:

a. Failed to tell Plaintiff, the public, physicians and the FDA that there were reported cases of this drug inducing lupus;

b. Concealed a material fact that certain persons would develop drug induced lupus;

c. Failed to adequately warn Plaintiff and/or others of the health hazards concerned with ingestion of minocycline;

d. Failed to recommend and/or provide proper cautions and warnings, to ensure Plaintiff's and/or other's safety;

e. Failed to warn Plaintiff and/or others of the danger and harm from consumption of minocycline;

f. Failed to instruct Plaintiff or others in the use of precautionary measures in relation to minocycline;

g. Failed to follow FDA procedures concerning product letters of approval;

h. Failed to advise Plaintiff, the public, and physicians when promoting this drug that a side effect was drug induced lupus;

i. Failed to seek immediate changes on its label when it was aware of reported cases of drug induced lupus;

j. Failed to inform AERS (Adverse Event Reporting System) of reported cases of drug induced lupus;

k. Failed to post marketing advertisement to warn health care professionals and consumers of the potential adverse event of drug induced lupus;

l. Failed to submit proposed label revisions to the FDA to include warnings for health care professionals and consumers of the potential for the adverse event of drug induced lupus;

m. Deliberately and intentionally did not warn Plaintiff or similarly situated persons that the drug minocycline was reported to have caused drug induced lupus.

35. Defendant intended that by not disclosing and/or concealing the material fact that there were reported cases of drug induced lupus, physicians would prescribe the drug and the public including Plaintiff would purchase the drug.

Federal Rule of Civil Procedure 9(b) "does not require plaintiff to plead detailed evidentiary matters." *D & G Enterprises v. Continental Illinois Nat. Bank and Trust Co. of Chicago,* 574 F.Supp. 263, 267 (D.C.Ill.,1983). The heightened pleading requirements for fraud

under F.R.C.P. 9(b) must be harmonized with F.R.C.P. 8. "Although [Rule 9] places stringent pleading requirements on a plaintiff, the Seventh Circuit has indicated that Rule 9 must be read in conjunction with Rule 8. Rule 8 requires 'a short and plain statement of the claim showing that the pleader is entitled to relief'." *Ambling v. Blackstone Cattle Co.,* 658 F.Supp. 1459, 1468 (N.D.Ill.1987) *citing Tomera v. Galt,* 511 F.2d 504, 508 (7th Cir.1975).

"Rule 9(b) does not require that the complaint explain the plaintiff's theory of the case, but only that it state the misrepresentation, omission, or other action or inaction that the plaintiff claims was fraudulent." *Midwest Commerce Banking Co. v. Elkhart City Centre*, 4 F.3d 521, 523 (C.A.7 (Ind.),1993), citing *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.1990) and *Bankers Trust Co. v. Old Republic Ins. Co.,* 959 F.2d 677, 682-83 (7th Cir.1992). "Most importantly, complaints charging fraud must sufficiently allege the defendant's fraudulent intent." *Graue,* 927 F.2d at 992, citing *Haroco v. American Nat'l Bank & Trust Co.,* 747 F.2d 384, 403 (7th Cir.1984).

Teva's Motion to Dismiss states that "[p]laintiff sets forth no specific facts to support her serious accusation that Teva has not complied with FDA regulations in connection with the reporting of adverse events for its minocycline drug," and that "[p]laintiff fails to allege any specific basis for concluding that Teva had any such knowledge concerning its drug." (Exh. B, Memorandum in Support of Defendant Teva Pharmaceuticals USA's Motion to Dismiss, at pg. 4). Plaintiff is not required to plead "detailed evidentiary matters," even under the heightened Rule 9(b) standards, and does not need to "explain the plaintiff's theory of the case" at this stage of the litigation. Plaintiff has sufficiently specified the "who, what, where, and when" of the fraudulent misrepresentations and concealment, and further details are properly saved for after

the discovery phase.[1] Plaintiff's allegations clearly state what defendant did (made false statements by not revealing to the FDA, plaintiff and physicians that this drug could cause drug induced lupus) during the time period plaintiff took the drug.

Furthermore, because the actions underlying a claim of fraudulent concealment are, by definition, concealed, a plaintiff must at a minimum demonstrate due diligence in inquiring into the circumstances surrounding the fraud. *See Tomera v, Galt*, 511 F.2d 504, 510 (7th Cir.1975). Plaintiff has demonstrated that due diligence through her attempts at furthering discovery in this case. Plaintiff's complaint is sufficiently specific, but even if it is not, defendant's refusal to provide evidence supporting its conclusory claims of compliance with federal law have thus far made it impossible for plaintiff to plead fraud with more specificity than it has provided.

2. Defendant's claim of federal preemption of Counts I and II fails because defendant's compliance with federal law is a question of fact, not of law, and dismissal of plaintiff's complaint under Rule 12(b)(6) is therefore inappropriate.

Teva's claim of federal preemption of state law rests on the assumption that Teva complied with federal law. Teva's motion to dismiss under F.R.C.P. 12(b)(6) asks the Court to accept without proof that Teva has complied with the FDA's requirements with respect to the labeling of Teva's Minocycline product. Teva so states in its brief, saying "Teva conformed its minocycline labeling in all material respects, including Warnings and Listed Adverse Reactions, to FDA approved label for Minocin®." (Exh. B at pgs. 12, 13). No evidence of compliance is presented either with that memorandum or in Teva's 26(a) response. Teva's compliance with

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[1]The specific facts of Teva's fraudulent concealment are not available to plaintiff without discovery. Plaintiff's discovery will allow plaintiff to plead with more specificity and address the issue of whether Teva fully complied with federal law. Defendant filed a motion to stay discovery in order to delay or prolong discovery unnecessarily, and therefore plaintiff has been unable to provide a more definite statement of the facts underlying Teva's liability.

federal law is a question of fact, not of law, and is therefore inappropriate for resolution by a 12(b)(6) motion. In deciding a 12(b)(6) motion, "[t]he court must accept all well-pleaded allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiffs." *Christensen v. County of Boone, IL* 483 F.3d 454, 457 (C.A.7 (Ill.),2007).

> A Rule 12(b)(6) motion to dismiss for failure to state a claim is granted only where it is beyond doubt that the plaintiff is unable to prove any set of facts that would entitle him to relief. *Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 102, 2 L.Ed.2d 80 (1957). The court must take all well pleaded facts and allegations as true and must view them in the light most favorable to the plaintiff. *Ellsworth v. City of Racine,* 774 F.2d 182, 184 (7th Cir.1985), *cert. denied,* 475 U.S. 1047, 106 S.Ct. 1265, 89 L.Ed.2d 574 (1986). Furthermore, plaintiff is entitled to all reasonable inferences that may be drawn from the complaint.

Sumpter v. Mack Chicago Corp. 918 F.Supp. 256, 259 (N.D. Ill. 1996).

Despite defendant's detailed explanation of FDA regulations, there is nothing to demonstrate that defendant actually complied with those regulations. Put simply, Teva's allegations of compliance with federal law are in opposition to plaintiff's claim that Teva did *not* comply with those same laws, and since Teva has moved for a motion to dismiss under F.R.C.P. 12(b)(6), plaintiff's statements should be accepted as true. Defendant's claims of compliance require evidentiary support, and are therefore questions of fact, which render them unsuitable for resolution by a 12(b)(6) motion.

WHEREFORE plaintiff respectfully requests that this Honorable Court deny defendant Teva's Motion to Dismiss.

Respectfully submitted,

By: s/ Michael P. Cascino
One of Plaintiff's Attorneys

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Certificate of Service

I hereby certify that on June 12, 2008, I electronically filed the foregoing with the Clerk of the U.S. District Court of the Northern District of Illinois using the CM/ECF system which sent notification of such filing to the following:

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